

# Test. Treat. Track.

Scaling up diagnostic testing, treatment and surveillance for malaria



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# Introduction

During the past decade, investments in malaria prevention and control have created unparalleled momentum and saved more than a million lives. Malaria death rates have been cut by over a quarter worldwide, and by one third in the World Health Organization (WHO) African Region. However, malaria transmission still occurs in 99 countries and the disease caused an estimated 655,000 deaths in 2010 (with an uncertainty range of 537 000 to 907 000 deaths), mainly among children under five years of age in sub-Saharan Africa. It is vital that malaria remains high on the political agenda in both malaria-endemic and donor countries, and that investments are scaled up further to support prevention, control and elimination efforts.

In 2008, United Nations Secretary General Ban Ki-moon set the target of achieving universal coverage with long-lasting insecticidal nets and other essential malaria control interventions by the end of 2010. With the distribution of more than 290 million nets in Africa between 2008 and 2010, significant progress was made towards achieving the target of universal bed net coverage for at-risk population groups. Indoor residual spraying, another highly cost-effective control intervention, has also been significantly scaled up, helping to cut malaria cases and deaths in hightransmission areas.

At the same time, however, the scale-up of diagnostic testing, treatment and surveillance has not received the same degree of attention. In the next few years, one of the biggest challenges will be to find the required resources to strengthen these three fundamental pillars of the existing global strategy to fight malaria. Such scale-up would allow endemic countries to make a major push towards achieving the health-related Millennium Development Goals and the World Health Assembly target of reducing the malaria burden by at least 75% by 2015.

# T3: Test. Treat. Track.

The WHO Global Malaria Programme's new initiative - T3: Test. Treat. Track. - will support malaria-endemic countries in their efforts to achieve universal coverage with diagnostic testing and antimalarial treatment, as well as in strengthening their malaria surveillance systems. The initiative seeks to focus the attention of policy-makers and donors on the importance of adopting WHO's latest evidence-based recommendations on diagnostic testing, treatment and surveillance, and updating existing malaria control and elimination strategies, as well as country-specific operational plans.

Malaria-endemic countries should ensure that every *suspected* malaria case is tested, that every *confirmed* case is treated with a quality-assured antimalarial medicine, and that the disease is tracked through timely and accurate surveillance systems to guide policy and operational decisions. The T3: Test. Treat. Track. initiative is built on a foundation of the following core WHO documents:

- Universal Access to Malaria Diagnostic Testing: an Operational Manual (2011)
- Guidelines for the Treatment of Malaria, Second Edition (2010)
- Disease Surveillance for Malaria Control & Elimination (2012)

By strengthening diagnostic testing, treatment and surveillance, affected countries will substantially improve child and maternal health, while lifting obstacles to education and economic development. The scale-up of these three interconnected pillars will provide the much-needed bridge between efforts to achieve universal coverage with prevention tools and the goal of eliminating malaria deaths, and eventually eradicating the disease. It will also lead to a better overall understanding of the disease burden and enable national malaria control programmes to better direct available resources to where they are most needed. Finally, it will allow for a more effective delivery of international aid programmes.

Strengthening these three pillars will present significant challenges, both financial and operational, but doing so is an indispensable step in the implementation of

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the comprehensive global malaria strategy. Tackling these challenges will require long-term commitment, high-level political support from malaria-endemic countries and donors, and close collaboration within the Roll Back Malaria Partnership. With malaria designated as one of the key priorities on the UN Secretary General's five-year action agenda (2012-2017), there is an unprecedented opportunity to fully implement our existing strategy, embrace the global targets, ensure accountability, and end unnecessary suffering.

### KEY FACTS ABOUT MALARIA

99 countries around the world have ongoing malaria transmission, and as many as 3.3 billion people are at risk of being infected.

According to WHO's estimates, approximately 216 million cases of malaria occurred in 2010 (uncertainty range: 149 million to 274 million) and the disease killed about 655,000 people (uncertainty range: 537 000 to 907 000).

86% of the victims are children under 5 years of age, and over 90% of malaria deaths occur in the WHO African Region.

About 44% of all estimated malaria deaths, or 290,000, occur in the two highest-burden countries: Nigeria and the Democratic Republic of the Congo.

Globally, the estimated incidence of malaria has been reduced by 17% since 2000 while malaria-specific mortality rates have declined by 26%.

In October 2011, Armenia was certified as free of malaria by WHO, becoming the fourth country in five years to eliminate malaria. The other three were the United Arab Emirates in 2007, Morocco in 2010, and Turkmenistan in 2010.

The number of long-lasting insecticidal nets delivered to malaria-endemic countries in sub-Saharan Africa increased from 88.5 million in 2009 to 145 million in 2010. An estimated 50% of households in sub-Saharan Africa now have at least one bed net.

A total of 185 million people were protected by indoor residual spraying (IRS) in 2010, representing 6% of the global population at risk. In sub-Saharan Africa, 11% of the population at risk is protected through IRS.



#### Universal Access to Malaria Diagnostic Testing: an Operational Manual (2011)

In the past, fever was equated with malaria in many endemic countries. However, recent control efforts have significantly reduced the malaria burden - even in high-transmission areas of Africa - and it has become clear that continued presumptive treatment of malaria would lead to both drug wastage and under-treatment of other febrile illnesses. In early 2010, WHO therefore recommended that every suspected malaria case be confirmed by microscopy or a rapid diagnostic test (RDT) prior to treatment. Only in areas where diagnostic testing is not possible should malaria treatment be initiated solely on clinical suspicion.

In recent years, the availability of high-quality, inexpensive RDTs has made it possible to significantly improve and expand parasitological diagnosis across all levels of the health system, from district hospitals to community-based programmes. As a result, the diagnostic testing rate has been increasing in all malaria-endemic regions of the world. In the WHO African Region, the rate of testing - among reported malaria cases in the public sector - rose from less than 5% in 2000 to 45% in 2010. However, most endemic countries in Africa are still far from achieving universal access to parasitological testing and will need to substantially expand access to microscopy and RDTs. In half of all endemic countries in Africa, over 80% of cases are still being treated without diagnostic testing.

Universal Access to Malaria Diagnostic Testing: an Operational Manual, released in 2011, provides a comprehensive roadmap for scaling up diagnostic testing and moving towards universal access. Accurate diagnosis will substantially improve the quality of care and ensure that antimalarial medicines are used rationally and correctly. Investing in an increased supply of RDTs in malaria-endemic countries will bring down the supply requirements for artemisinin-based combination therapies

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(ACTs), which are the most effective medicines for uncomplicated malaria cases caused by *Plasmodium falciparum*. Countries that have already scaled up diagnostic testing are saving hundreds of thousands of ACT courses every year, and, in the process, a lot of money as well.

Microscopy and RDTs have unique characteristics which make each useful in particular situations and settings. Therefore, the introduction or expansion of one should not replace but rather complement the other. To strengthen malaria diagnostic testing, the diagnostic tools must be accurate and of highquality, and they must be properly used. This requires: accurate quantification and forecasting of need; procurement of appropriate tests and supplies; quality assurance across all levels of the health system; effective supply chain management; health worker training and supervision; and consistent monitoring and evaluation of programmes. The Operational Manual contains guidance and practical tools for all of these areas.

The scale-up of diagnostic testing presents an unprecedented opportunity to improve the accuracy of malaria surveillance data, which in turn helps ministries of health to better direct available resources to where they are most needed. These efforts will improve quality of care and will enable national malaria control programmes to respond promptly to surges in malaria, whether caused by failure to maintain coverage with malaria control interventions, climate change, antimalarial drug resistance, or mosquito resistance to insecticides.

The expansion of diagnostic testing will also rationalize antimalarial drug use, and increase public trust in health care workers and in the effectiveness of antimalarials. It is key that malaria diagnostic testing is deployed as an integral component of programmes aiming to improve management of all febrile patients, including illnesses other than malaria.

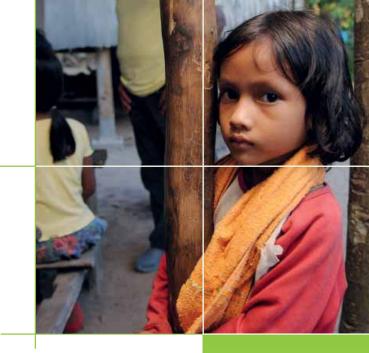
#### QUICK FACTS

- The number of RDTs delivered by manufacturers increased from 45 million in 2008 to 88 million in 2010.
- In 2010, 37 out of 43 endemic countries in the WHO African Region, and 53 out of 63 countries in other WHO Regions, reported having adopted the policy of providing malaria diagnostic testing for all age groups.
- Despite this progress, the number of diagnostic tests carried out in 2010 in Africa was still less than half the total number of ACTs procured and distributed.

# KEY **RECOMMENDATIONS**

- Every suspected malaria case should be confirmed by microscopy or RDT prior to treatment
- All diagnostic tools must be quality-assured across all levels of the health system
- Scale-up of malaria diagnostic testing should be integrated with efforts to improve the management of other febrile illnesses

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# Treat.

## Guidelines for the Treatment of Malaria, Second Edition (2010)

Malaria is an entirely preventable and treatable disease. Millions of lives are saved each year by prompt antimalarial treatment. However, despite the availability of effective, high-quality antimalarials, millions of people in endemic countries still lack ready access to appropriate treatment. While significant progress has been made in recent years, countries must continue to ensure access to quality of care in both the public and private sectors, and strive to treat every patient with quality-assured antimalarials.

Prompt and appropriate treatment of uncomplicated malaria is critical to preventing progression to severe disease, as well as to reducing the overall parasite reservoir in a community. WHO recommends ACTs as the first-line treatment for uncomplicated malaria cases caused by *P. falciparum*. Only medicine combinations whose efficacy has been demonstrated through routine monitoring should be used.

Severe *P. falciparum* malaria can lead to the death of a patient and must be treated as a medical emergency. WHO recommends the administration of rectal artesunate for children with severe malaria as pre-referral treatment, prior to transfer to an appropriate health facility for further care. Injectable artesunate is recommended for the definitive treatment of severe *P. falciparum* malaria in both children and adults in all geographical settings. If intravenous (IV) or intramuscular (IM) artesunate is not available, IV/IM quinine remains an acceptable alternative. Following initial treatment, it is essential to treat patients with a complete course of an effective ACT.

*P. vivax* malaria - which is the predominant parasite species responsible for malaria in large parts of South Asia and parts of Latin America - should be treated with chloroquine where the drug is effective, or an appropriate ACT in areas where *P. vivax* is resistant to chloroquine. Complete treatment of *P. vivax* should include a 14-day course of daily primaquine in patients (except in persons with glucose-6-phosphate dehydrogenase (G6PD) deficiency) in order to prevent relapses.

In 2010, 181 million ACT courses were procured worldwide in the public sector, up from 158 million in 2009, and just 11 million in 2005. Total ACT demand was projected to reach 287 million courses in 2011, an increase of more than 30% over that in 2010, in part because of increased subsidized sales in the private sector.

Published in 2010, and updated on-line in 2011, the second edition of the *Guidelines for the Treatment of Malaria* lists all of WHO's evidence-based recommendations for the treatment of malaria in all endemic regions of the world. The recommendations are based on the latest scientific evidence reviewed by the WHO Technical Expert Group on Malaria Chemotherapy, and can be applied even in settings that are severely resource-constrained. The guidelines provide a framework for the development of detailed national treatment protocols that need to take into account local antimalarial drug resistance patterns and health service capacities.

During the past few years, *P. falciparum* resistance to artemisinins has been detected in the Greater Mekong sub-region of South East Asia and is becoming a major threat to malaria control efforts. To prevent the spread of antimalarial drug resistance, WHO emphasizes the importance of universal diagnostic testing, adherence to full courses of prescribed antimalarial regimens, and the dispensing of only quality-assured antimalarials. Equally critical are: the use of fixed-dose combinations rather than loose or co-blistered combinations (use of the former improves patient adherence to recommended regimens); the routine monitoring of the therapeutic efficacy of antimalarials; and bringing an end to the use of oral artemisinin-based monotherapies.

Many patients are still being treated in the private sector with oral artemisinin-based monotherapies, as well as spurious, falsely labelled, falsified, counterfeit, and substandard medicines. This is due to weak regulation and poor enforcement of quality standards in many endemic countries, as well as to limited access to appropriate combination therapies.

#### **QUICK FACTS**

- By the end of 2010, 84 countries had adopted ACT as the first-line treatment for *P. falciparum* malaria.
- In 2010, 60 countries were providing ACTs free of charge for all age groups in the public sector. Meanwhile, 55 countries were undertaking therapeutic efficiency monitoring.
- Artemether-lumefantrine (AL) accounted for the largest volume of ACTs procured by the public sector (70%) in 2010.

## KEY **RECOMMENDATIONS**

- After diagnostic confirmation, every uncomplicated case of *P. falciparum* malaria should be treated with a quality-assured ACT
- Every severe case of *P. falciparum* malaria should be treated with intravenous or intramuscular artesunate, followed by a full course of an ACT

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- Antimalarials should be routinely monitored for therapeutic efficacy



# Disease Surveillance for Malaria Control & Elimination (2012)

WHO urges malaria-endemic countries to strengthen their disease surveillance, health information and vital registration systems, so that ministries of health can better identify public health priorities and design effective health interventions.

Improved surveillance for malaria cases and deaths will help ministries to determine which areas or population groups are most affected and help to target resources to communities most in need. Scaled-up surveillance will also enable ministries to promptly identify resurgences in malaria should they occur, and to maximize the efficiency of malaria prevention and control programmes. Information on malaria incidence in relation to historical levels can also alert ministries to epidemics, so that control measures can be intensified. Finally, data on changing malaria trends is indispensable to judge the success of programme implementation and to determine whether adjustments are required in the scale or blend of interventions.

The design of malaria surveillance systems depends on two fundamental factors the level of malaria transmission, and the resources available to conduct surveillance. In April 2012, WHO released two manuals to help endemic countries strengthen their malaria surveillance. One of the manuals is for countries engaged in malaria control while the other is for countries conducting malaria elimination programmes. The manuals describe the general principles of surveillance; recommended case definitions and core indicators; procedures for data recording, reporting and analysis; and guidance on the establishment of surveillance systems. The manuals also contain templates for recording, reporting and investigating malaria cases.

In high-burden countries, malaria cases are so numerous that it is not possible to examine and react to each confirmed case individually. National malaria control programmes therefore need to base their analysis on aggregate numbers and undertake action on a population level. WHO recommends that national malaria control programmes report regularly on suspected, presumed and confirmed cases to WHO, and track trends in changing incidence and mortality across the country. As scaled-up malaria prevention and control interventions gradually reduce malaria transmission, it becomes increasingly possible, and necessary, to track and respond to individual cases.

Thus, in elimination settings, surveillance systems should seek to identify and immediately provide notification of all malaria infections, whether they are symptomatic or not. Imported cases may comprise a significant proportion of all cases, and may pose a risk to re-establishment of transmission in areas where malaria has been eliminated. WHO recommends that countries in this phase make resources available to investigate each case, ascertain whether or not it is imported or locally acquired, and undertake appropriate response measures.

There are no strict rules as to when countries should transition between the different approaches to surveillance. Such decisions depend on the levels of malaria transmission and the capacity of control programmes to perform specific surveillance activities. Some countries in relatively high transmission settings may be able to adopt some approaches used in low transmission settings (and their control programmes would be expected to progress more rapidly as a result of better targeting of interventions). Different approaches may also be used in different settings within a country, particularly where transmission intensity varies geographically.

#### **QUICK FACTS**

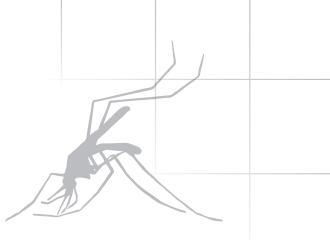
- Between 2000 and 2010, 43 malaria-endemic countries achieved an over 50% reduction in their number of malaria cases. Another 8 countries recorded decreases of more than 25%.
- It was not possible to ascertain malaria trends with certainty in 38 of 99 countries with ongoing transmission owing to weaknesses in surveillance systems.
- In 2010, there were 80 countries in malaria control phase and 10 countries in elimination phase. An additional 9 countries were classified by WHO to be in pre-elimination phase, and 7 others in the prevention of reintroduction phase.

# KEY **RECOMMENDATIONS**

- Individual cases should be registered at health facility level. This allows for the recording of suspected cases, diagnostic test results, and treatments administered
- In the malaria control phase, countries should report suspected, presumed and confirmed cases separately, and summarize aggregate data on cases and deaths on a monthly basis
- Countries in elimination phase should undertake a full investigation of each malaria case

This CD ROM contains the core documentation cited in this brochure, as well as additional T3-related publications from the Global Malaria Programme. The files can also be downloaded from www.who.int/malaria. Please visit the site regularly for updated versions of the *World Malaria Report* and our technical documents containing evidence-based norms, standards, policies and guidelines.





#### About the WHO Global Malaria Programme

The WHO Global Malaria Programme has four essential roles: 1) to set, communicate, and promote the adoption of evidence-based norms, standards, policies, and guidelines; 2) to keep independent score of global progress against malaria; 3) to develop approaches for capacity building, systems strengthening and surveillance; and 4) to identify threats to malaria control and elimination, as well as new opportunities for action. The department's flagship annual publication, the *World Malaria Report*, contains the latest available data on the impact of malaria interventions around the world. The department supports 99 countries with ongoing malaria transmission in their fight against this disease, and works with a wide group of stakeholders under the aegis of the Roll Back Malaria Partnership to achieve its aims.

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